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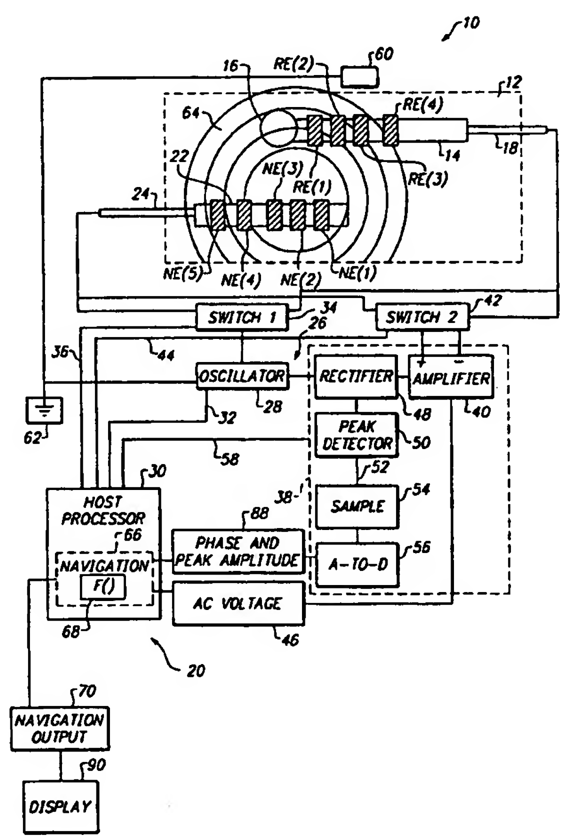
(54) Title: SELF-CALIBRATING SYSTEMS AND METHODS FOR LOCATING AND GUIDING OPERATIVE ELEMENTS WITHIN THE INTERIOR OF LIVING BODIES

(57) Abstract

Calibrated systems and methods locate a roving structure inside a body region. An electric field is established inside the body region between an electrical energy transmitting electrode and an electrical reference. A navigational output is derived for the roving structure based upon a function, which expresses a relationship between an electrical characteristic sensed at the roving structure and distance between the roving structure and the electrical energy transmitting electrode. First and second electrodes, spaced apart a known distance, are present in the electric field. The function is adjusted by comparing the known distance to at least one derived navigation output, which is derived, based upon the function, by sensing an electrical characteristic at the first and second electrodes.



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SELF-CALIBRATING SYSTEMS AND METHODS FOR LOCATING AND GUIDING OPERATIVE ELEMENTS WITHIN THE INTERIOR OF LIVING BODIES

FIELD OF THE INVENTION

The invention generally relates to systems and methods for guiding or locating diagnostic or therapeutic elements in interior regions of the body.

BACKGROUND OF THE INVENTION

Physicians make use of catheters today in medical procedures to gain access into interior regions of the body for diagnostic and therapeutic purposes. It is important for the physician to be able to reliably and precisely position in proximity to desired tissue locations.

SUMMARY OF THE INVENTION

The invention provides calibrated systems and methods for locating a roving structure inside a body region by use of an electric field established inside the body region between an electrical energy transmitting electrode and an electrical reference. The systems and methods derive a navigational output for the roving structure based upon a function, which expresses a relationship between an electrical characteristic sensed at the roving structure and distance between the roving structure and the electrical energy transmitting electrode. The systems and methods place in the electric field first and second electrodes, which are spaced apart by a known distance. The systems and methods adjust the function by comparing the known distance to at least one derived navigation output derived, based upon the

function, by sensing an electrical characteristic at the first and second electrodes. In one embodiment, one of the first and second electrodes comprises the electrical energy transmitting electrode.

In one embodiment, the roving structure carries the first and second electrodes. In an alternative embodiment, a navigation structure, separate from the roving structure, carries the first and second electrodes.

In one embodiment, the systems and methods provide a code, which identifies the known distance. In this embodiment, the systems and methods upload the code for use in calibration.

In one embodiment, the systems and methods sense an electrical characteristic at the first electrode at one point in time and sense an electrical characteristic at the second electrode at a different point in time.

In one embodiment, the function on which the navigation output is based includes a coefficient. The systems and methods adjust the coefficient based upon a comparison of the derived navigation output and the known distance, e.g., to minimize variance between the derived navigation output and the known distance, or to optimize the coefficient.

Other features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic view of a navigation unit, which generates a navigation output to assess

and track the position of an instrument deployed within a targeted body region;

Fig. 2 is a schematic view of the navigation and calibration functions of the navigation unit shown in Fig. 1;

Fig. 3 is a schematic view of the navigation algorithm, which provides a navigation output indicating proximity of a deployed instrument to a navigation electrode located in the targeted body region;

Fig. 4 is a schematic view of the deployment of multiple navigation reference probes in a targeted body region to assess and track the position of an instrument deployed in the region; and

Fig. 5 is a schematic view of a graphical user interface (GUI), which can be used to present the navigation output of the navigation unit shown in Fig. 1.

The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 shows a system 10 for diagnosing, treating or otherwise administering health care to a targeted tissue region in a patient.

The system 10 is well adapted for use inside body lumens, chambers or cavities for either

diagnostic or therapeutic purposes. For this reason, the system 10 will be described in the context of its use within a living body.

The system 10 also lends itself to catheter-based procedures, where access to the interior body region is obtained, for example, through the vascular system or alimentary canal, without complex, invasive surgical procedures. For example, the system 10 can be used during the diagnosis and treatment of arrhythmia conditions within the heart, such as ventricular tachycardia or atrial fibrillation. The system 10 also can be used during the diagnosis or treatment of intravascular ailments, in association, for example, with angioplasty or atherectomy techniques. The system 10 also can be used during the diagnosis or treatment of ailments in the gastrointestinal tract, the prostrate, brain, gall bladder, uterus, liver, and other regions of the body.

A. THE ROVING OPERATIVE ELEMENT

The system 10 includes a diagnostic or therapeutic instrument 14. The instrument 14 carries an operative element 16 usable for a diagnostic or therapeutic purpose in the targeted tissue region 12.

The operative element 16 can, for example, comprise a device for imaging body tissue, such as an ultrasound transducer, or an array of ultrasound transducers, or an optic fiber element, or a CT or MRI scanner. Alternatively, the operative element 16 can comprise a device, e.g., a needle or cannula, to deliver a drug or therapeutic material to body tissue. Still alternatively, the operative element 16

can comprise a device, e.g., an electrode, for sensing a physiological characteristic in tissue, such as electrical activity in heart or nerve tissue, or for transmitting energy to stimulate or ablate tissue.

When deployed in the body, the operative element 16 is intended to be mobile and capable of roving about the targeted tissue region 12 under the direction of the physician. For this reason, the element 16 will also sometimes be called a "roving instrument."

For roving deployment in the targeted tissue region 12, the operative element 16 is preferably carried at the distal end of a catheter tube 18. Nevertheless, it should be appreciated that the system 10 can also be used in association with systems and methods that are not necessarily catheter-based, e.g., laser delivery devices, atherectomy devices, transmyocardial revascularization (TMR), percutaneous myocardial revascularization (PMR), or hand held surgical tools.

B. THE NAVIGATION UNIT

The system 10 also includes a navigation unit 20. The navigation unit 20 monitors the position and tracks the movement of the roving operative element 16 in the targeted tissue region 12.

(1) The Locating Probe

The navigation unit 20 includes a navigation reference probe 22. In the illustrated embodiment, the navigation reference probe 22 takes the form of an elongated array of navigation electrodes NE(i), where i = 1 to n, and where NE(1) denotes the most

distal navigation electrode and NE(n) denotes the most proximal electrode. In the illustrated embodiment, n = 5.

In the illustrated embodiment, the navigation electrodes NE(i) take the form of conventional rings of electrically conductive material (e.g., copper alloy, platinum, or stainless steel), arranged in a spaced apart, segmented relationship about a sleeve of electrically insulating material. Alternatively, the navigation electrodes NE(i) can be coated upon the sleeve using conventional coating techniques or an ion beam assisted deposition (IBAD) process, or comprise spaced apart lengths of wound, spiral coils made of electrically conducting material.

The reference probe 22 can assume different shapes. For example, the probe 22 can comprise a three dimensional array of electrodes, which assume a basket-like shape, like the CONSTELLATION® Catheter sold by EP Technologies, Inc.

Regardless of its particular construction, the spacing among the electrodes NE(i) on the probe 22 is set during manufacture. Preferably, the spacing values for the navigation reference probe 22 are accessible to the navigation unit, to enable self-calibration, as will be described in greater detail later.

In the illustrated embodiment, the navigation reference probe 22 is carried at the distal end of a catheter tube 24 for deployment within the targeted tissue region 12 through the vasculature. The navigation reference probe 22 can be placed at or near known anatomic regions within the region 12,

using, for example, fluoroscopy or another imaging technology, such as ultrasound. The reference probe 22 may also be positioned in contact with tissue or a vascular region surrounding the region 12. The reference probe 22 may also be positioned in contact with skin on the exterior of the patient's body. As will be described in greater detail later, more than one reference probe 22 may be located in or about the region 12 to provide multi-planar navigation points, making triangulation possible.

The navigation unit 20 also includes an array of roving electrodes RE(j) on the instrument 14, where j = 2 to m, and where RE(1) denotes the most distal roving electrode and RE(m) denotes the most proximal roving electrode. In the illustrated embodiment, m = 4.

In the illustrated embodiment, the most distal roving electrode RE(1) is designated the main marker electrode for navigation purposes, as will be described in greater detail later. The remaining roving electrodes RE(2) to RE(4) on the instrument 14 comprise calibration electrodes. As will be described later, the calibration electrodes RE(2) to RE(4) are used to optimize the operation of the navigation unit 20 based upon the physical and electrical properties of the marker electrode RE(1), as well as the morphology of the targeted body region 12.

It should be appreciated that any given roving electrode RE(j) may serve either as the main marker electrode or as a calibration electrode. In this respect, the main marker electrode need not be the

distal most roving electrode, but can be any electrode carried by the instrument 14.

The spacing among the roving electrodes RE(j) is set during manufacture. The spacing values are accessible to the navigation unit 20, which applies them during calibration, as will be described later.

The roving electrodes RE(j) may be components added to the instrument 14 strictly for navigational purposes. Alternatively, the roving electrodes RE(j) may comprise components used by the instrument 14 for purposes in addition to navigation.

In the illustrated embodiment, the roving electrodes RE(j), like navigation electrodes NE(i), take the form of conventional rings of electrically conductive material (e.g., copper alloy, platinum, or stainless steel), arranged in a spaced apart, segmented relationship about a sleeve of electrically insulating material. Alternatively, like the navigation electrodes NE(i), the roving electrodes RE(j) can be coated upon the sleeve using conventional coating techniques or an ion beam assisted deposition (IBAD) process, or comprise spaced apart lengths of wound, spiral coils made of electrically conducting material.

(2) The Signal Processing Element

Still referring to Fig. 1, the navigation unit 22 includes a signal processing element 26. The processing element 26 includes an oscillator 28, which is coupled to a host processor 30 by a control bus 32. The host processor 30 conditions the oscillator 28 to generate an AC wave form at a predetermined amplitude and frequency.

The signal processing element 26 also includes a first electronic switch element or multiplexer 34. An address bus 36 couples the host processor 30 to the first electronic switch element 34, which is, in turn, coupled to each navigation electrode NE(i) and to each roving electrode RE(j). By commanding the switch element 34, the host processor 30 can distribute the AC output of the oscillator 28 in a prescribed fashion to either one or more navigation electrodes NE(i) or to one or more roving electrodes RE(j).

The signal processing element 26 also includes a data acquisition module 38. The data acquisition module 38 includes a differential amplifier 40, which is coupled via a second electronic switch element or multiplexer 42 to each navigation electrode NE(i) and each roving electrode RE(j). The host processor 30 conditions the second switch element 42 via a second address bus 44 to couple a selected roving electrode RE(i) or a selected navigation electrode NE(i) to either the inverting (-) input or noninverting (+) input of the differential amplifier 40.

The output of the amplifier 40 is a differential AC voltage signal 46, which is communicated to the host processor 30 for processing, as will be described later.

In this arrangement, the signal processing element 26 can couple the oscillator 28 to any navigation electrode NE(i) or any roving electrode RE(j) to transmit energy. The signal processing element 26 can also sense an electrical potential at

any navigation electrode NE(i) or any roving electrode RE(j).

In the illustrated embodiment (see Fig. 1), the data acquisition module 38 also includes a synchronized rectifier 48 and a peak detector 50. The rectifier 48 receives the AC signal voltage output of the amplifier 40 and senses its phase relative to the phase at the output of the oscillator 28. The detector 50 determines the peak amplitude of the AC voltage signal output of the amplifier 40.

The output of the detector 50 is an analog signal 52 having a value corresponding to the peak amplitude of the AC output of the amplifier 40, and a sign (+ or -) denoting whether the AC voltage output is in phase with the oscillator 28 (+) or out of phase with the oscillator 28 (-).

The data acquisition module 38 registers this analog signal 52 in association with the electrodes then-coupled to the amplifier 40 in a sample and hold element 54. An analog to digital converter 56 converts the analog signals 52 to digital phase and peak amplitude signals 88 for processing by the host processor.

A suitable control bus 58 couples the components of the data acquisition module 36 to the host processor 30 for coordination and control functions. The host processor 30, e.g., sets the sampling rate of the sample and hold element 54, the input range of the converter 56, and the amplification of the amplifier 40.

a. The Navigation Mode

In the illustrated embodiment (Fig. 1), the host processor 30 is capable of operation in a navigation mode. In this mode, the host processor 30 conditions the oscillator 28 to generate an electrical alternating current (AC) waveform at a predetermined amplitude and frequency.

For use within a living body space, the selected current amplitude of the oscillator 28 output can vary between 0.1 mAmp to about 5 mAmp. The frequency selected can also vary from about 5 kHz to about 100 kHz. Currents substantially above about 5 mAmp and frequencies substantially below 5 kHz should be avoided when heart tissue is nearby, as they pose the danger of inducing fibrillation. The maximum current that can be used while avoiding fibrillation is a function of the frequency, as expressed in the

$$I = f \times 10$$

following equation:

where I is current in µAmp (RMS), and f is frequency in kHz.

The shape of the waveform can also vary. In the illustrated and preferred embodiment, the waveform is sinusoidal. However, square wave shapes or pulses can also be used, although harmonics may be encountered if capacitive coupling is present. Furthermore, the waveform need not be continuous. The oscillator 28 may generate pulsed waveforms.

The host processor 30 commands the first switch element 34 to transmit the electrical waveform supplied by the oscillator 28 through a selected one or more navigation electrodes NE(i). An indifferent

electrode 60, e.g., carried as a patch on the exterior of the patient, comprises the voltage return, which is, in turn, coupled to an electrical reference 62. In the illustrated embodiment, the electrical reference 62 is isolated or patient ground, although other references can be used. Alternatively, a navigation electrode NE(i) not serving to transmit the electrical waveform can serve as the voltage return.

The transmission of electrical energy from the transmitting navigation electrode NE(i) to the indifferent electrode 60 establishes a voltage field 64. The voltage field 64 extends from the transmitting electrode into the targeted tissue region 12. The field 64 surrounds the roving instrument 14 present within the region 12.

The host processor 30 conditions the data acquisition module 38 to sense local voltages within the field 64 between the transmitting navigation electrode or electrodes and the marker electrode RE(1). For example, in a preferred embodiment, the data acquisition module 38 senses voltage amplitudes at the transmitting electrode NE(i) and marker electrode RE(j).

The data acquisition module 38 can also be conditioned to sense other electrical characteristics in the field 64 in addition to voltage amplitudes. For example, using the rectifier 48 and detector 50, the data acquisition module 38 can acquire spacial variations in phase or spacial variations in waveform within the field. The data acquisition module 38 can also acquire variations in impedances between the

transmitting navigation electrode NE(i) and the market electrode RE(1).

The host processor 30 inputs the electrical field data signals 46 and 88 into a prescribed navigation algorithm 66, which resides on the host processor 30. The algorithm 66 includes prescribed functions 68, which processes sensed electrical field data based upon empirically derived mathematical coefficients and weighing factors to generate a navigation output 70. The navigation output 70 indicates the position of the marker electrode RE(1) relative to one or more navigation electrodes NE(i). The navigation output 70 thereby provides an instantaneous indication of the position of the roving instrument 14 and, over time, also tracks the movement of the roving instrument 14 within the targeted tissue region 12.

In the illustrated embodiment (Fig. 1), the navigation unit 20 includes a display device 90 (e.g., a CRT, LED display, or a printer). The device 90 presents the navigation output 70 in a visual format useful to the physician for remotely locating and guiding the instrument 14 within the targeted tissue region 12. Further details of the display device 90 will be described later.

The technique for acquiring and processing sensed electrical field data can vary. In a preferred embodiment (see Fig. 2), the algorithm 66 processes the local amplitude values 46 of the voltage field sensed by the main marker electrode RE(1). The local voltage amplitude values vary based upon a determinable voltage-to-distance function 72, as the

distance between the sensing electrode RE(j) and the transmitting electrode NE(i) varies.

To acquire voltage amplitude data, the data acquisition module 38 conditions the navigation electrode NE(i) that is currently transmitting the electrical field (which will also be called the "transmitting electrode") to itself sense a local voltage amplitude, or $V_{NE(i)}$. The data acquisition module 38 also conditions the main marker electrode RE(1)on the operative element to sense a local voltage amplitude, or $V_{RE(1)}$, at the same time $V_{NE(i)}$ is sensed by the transmitting electrode NE(i). $V_{RE(1)}$ is acquired in association with each $V_{NE(i)}$.

Based upon this input, the navigation algorithm 66 derives a normalized detected voltage value, designated $V_{N(1,i)}$, for each acquired $V_{RE(1)}$ and $V_{NE(i)}$

$$V_{N(1,i)} = \frac{V_{RE(1))}}{V_{NE(i)}}$$

data set, as follows:

More universally expressed, the normalized detected voltage value V_N is derived by dividing the local voltage amplitude sensed by the transmitting electrode (universally designated V_{TRANS})into the local voltage amplitude sensed by the other non-transmitting, sense-only electrode (universally

$$V_N = \frac{V_{SENSE}}{V_{TRANS}}$$

designated V_{SENSE}), or:

Applying this more universal expression, the navigation unit 20 can obtain electrical field data by coupling the oscillator 28 to any roving electrode RE(j) to generate the electric field between it and the indifferent electrode 60. Alternatively, another roving electrode RE(j) not serving to transmit the energy field, or one of the navigation electrodes NE(i), can serve as the voltage return. In this alternative implementation, the data acquisition module 38 individually conditions a selected navigation electrode NE(i) (or, in sequence, several navigation electrodes) to sense a local voltage amplitude $V_{NE(i)}$, which corresponds to the quantity V_{SENSE} in Equation (3). The data acquisition module 38 also conditions the transmitting roving electrode RE(j) to itself sense a local voltage amplitude $V_{RE(j)}$ at the same time $V_{NE(i)}$ is sensed by each navigation electrode NE(i), which corresponds to the quantity V_{TRANS} in Equation (3).

In this arrangement, the algorithm 66 derives a normalized detected voltage value $V_{N(i,j)}$ for each

$$V_{N(i,j)} = \frac{V_{NE(i)}}{V_{RE(j)}}$$

acquired $V_{RE(j)}$ and $V_{NE(i)}$ data set, as follows:

The algorithm 66 (see Fig. 2) incorporates a voltage-to-distance function 72, according to which the normalized voltage V_N (i.e., V_{SENSE}/V_{TRANS}) decays to zero as the distance between the sensing electrode (E_S) and the transmitting electrode (E_T) [or $d(E_s-E_T)$] increases.

The voltage-to-distance function 72 relating normalized voltage V_N to the navigation output $d(E_S-E_T)$, can be mathematically expressed, e.g., as

$$V_N = f(\lambda_1, \lambda_2, \ldots, \lambda_x, d(E_S - E_T))$$

follows:

In Equation (5), f is a continuous, monotonically decreasing function. The quantities $\lambda_{1\text{-to-}x}$ are coefficients and weighing factors, which can be determined and assigned values experimentally, e.g., by *in vitro* or *in vivo* testing or by finite element analysis.

Because the function f is continuous and monotone, the navigation output $d(E_S-E_T)$ can itself be expressed as a unique inverse function f^{-1} of the normalized voltage V_N, as well as inverse coefficients and weighing factors $\gamma_{1\text{-to-}n}$, e.g., as

$$d(E_S - E_T) = f^{-1}(\gamma_1, \gamma_2, \ldots, \gamma_y, V_N)$$

follows:

The inverse function f^{-1} of Equation (6) can be approximated using various numeric methods. For example, approximation by Taylor series could be used.

Applying the inverse function f^{-1} based upon sensed electrical conditions in the field, the navigation algorithm 66 generates the navigation output 70, which expresses $d(E_S-E_T)$.

In addition to the empiric voltage-to-distance function 72, the navigation algorithm 66 can apply other empiric functions 74 (see Fig. 2) which include

coefficients and weighing factors expressing relationships between distance and the spacial distribution of voltage gradients sensed in the field 64. For example, the navigation algorithm 66 can include in the generation of the navigation output 70 the application of coefficients and weighing factors relating changes in position to variations in phase sensed in the field, as disclosed in copending Patent Application Serial No. 08/320,301, filed October 11, 1994, and entitled "Systems and Methods for Guiding Movable Electrode Elements Within Multiple Electrode Structures." As another example, the navigation algorithm 74 can also include in the generation of the navigation output 70 the application of coefficients and weighing factors relating changes in position to variations in waveform sensed in the field, as disclosed in copending Patent Application Serial No. 08/745,795, filed November 8, 1996, and entitled "Systems and Methods for Locating and Guiding Operating Elements Within Interior Body Regions." Further discussion of these alternative functions 74 will appear later.

b. The Calibration Mode

Empiric voltage-to-distance functions 72 or empiric voltage gradient-to-distance functions 74, as above discussed, can introduce procedure-specific and patient-specific errors, e.g., due to physical and electrical differences in electrodes, as well as differences the thoracic morphology or each patient. To minimize these errors, the navigation unit 20 includes a calibration element 76 (see Fig. 2).

The calibration element 76 can be called into operation, e.g., at the outset of a diagnostic or therapeutic procedure. Operating in a calibration mode, the calibration element 76 acquires voltage amplitude information and iteratively adjusts the coefficients and weighing factors in the voltage- or voltage gradient-to-distance functions 72 and 74 of the navigation algorithm 66, to more closely reflect actual, as opposed to theoretical, conditions.

In the illustrated embodiment, four roving electrodes are shown as RE(1) (the main marker electrode), RE(2), RE(3), and RE(4). As before disclosed, the spacing among the roving electrodes RE(1, 2, 3, 4) is set during manufacture and is known. As Fig. 2 shows, the calibration element 76 includes an input 78 for receiving the established spacing values among the main marker electrode RE(1) and the other roving electrodes RE(2, 3, 4).

For purpose of illustration, these set spacing values can be designated d(E2-E1), denoting the spacing between RE(1) and RE(2); d(E3-E1), denoting the spacing between RE(1) and RE(3); and d(E4-E1)denoting the spacing between RE(1) and RE(4). The input 78 can, for example, comprise a keyboard, which the physician uses to manually input the spacing values d(E2-E1), d(E3-E1), and d(E4-E1), based upon values provided with the operating instructions for instrument 14.

In the illustrated embodiment, the instrument 14 includes a coded component 80. The coded component 80 carries an identification code, which uniquely identifies selected physical properties of the

instrument 14, including the spacing values for the roving electrodes RE(j) it carries. The coded component 80 can be located, e.g., within a handle (not shown) attached at the proximal end of the catheter tube 18 that carries the operative element 16.

The coded component 80 can, for example, take the form of an integrated circuit, which expresses in digital form the code for input in ROM chips, EPROM chips, RAM chips, resistors, capacitors, programmed logic devices (PLD's), or diodes. Examples of catheter identification techniques of this type are shown in Jackson et al. United States Patent 5,383,874, which is incorporated herein by reference. Alternatively, the coded component 80 can comprise several resistors having different resistance values. The different independent resistance values express the digits of the code

The calibration element 76 includes an interpreter 84, which automatically inputs the code when the instrument 14 is coupled to the input 78. The interpreter 84 compares the input code to, for example, a preestablished master table of codes contained in memory. The master table lists, for each code, the physical characteristics of the instrument 14, including the spacing values d(E2-E1), d(E3-E1), and d(E4-E1).

The spacing values d(E2-E1), d(E3-E1), and d(E4-E1) are communicated to a calibration algorithm 86. The algorithm 86 forms a system of equations based upon the voltage-to-distance function 72, such as in preceding Equation (6), e.g., as follows:

$$d(E_j - E_1) = f^{-1}(\gamma_1, \gamma_2, \ldots, \gamma_m, \frac{V_{Ej}}{V_E} 1)$$

where j = 2-to-m (in the illustrated embodiment, m = 4).

Under command of the host processor 30 during the calibration mode, the data acquisition module 38 conditions the main marker electrode RE(1) to transmit electrical energy to the indifferent electrode 60, thereby establishing an electrical field 64. The data acquisition module 38 also conditions the main marker electrode RE(1) to sense a local voltage amplitude $V_{RE(1)}$. At the same time, the data acquisition module 38 individually conditions the other roving electrodes RE(2), RE(3), and RE(4) to sense local voltage amplitudes, respectively $V_{RE(j)}$, where j=2-to-4, or $V_{RE(2)}$, $V_{RE(3)}$, and $V_{RE(4)}$. The data acquisition module 38 acquires the sensed local voltage amplitudes $V_{E(2)}$, $V_{RE(3)}$, and $V_{RE(4)}$. The calibration algorithm 86 derives the normalized detected voltage values $V_{N(2)}$ (or $V_{RE(2)}/V_{RE(1)}$); $V_{N(3)}$ (or $V_{RE(3)}/V_{RE(1)}$); and $V_{N(4)}$ (or $V_{RE(4)}/V_{RE(1)}$).

The calibration algorithm 86 optimizes the coefficients $\gamma_{1\text{-to-}y}$ in the Equation (7) at each normalized voltage value $V_{N(2)}$; $V_{N(3)}$; and $V_{N(3)}$ to yield a navigation output 70 which equals or approaches the actual spacing values d(E2-E1), d(E3-E1), and d(E4-E1). In the illustrated embodiment, the optimization yields, for each normalized voltage $V_{N(2)}$, $V_{N(3)}$, and $V_{N(4)}$, the least square error between the calculated distance (i.e., the navigation output 70) and the known spacing distance.

Various conventional optimization techniques can be used, e.g., steepest descent, least-mean-squares, or least-recursive squares. By way of example, if $\delta(E_j-E_1)$ is assigned to represent the known spacing

$$\xi_j=(\delta(E_j-E_1)-d(E_j-E_1))^2$$

value (j = 2-to-4), then the quantity: represents the square errors that must be minimized. When best optimized in the illustrated embodiment, these errors will equal zero for j = 2-to-4. The calibration algorithm 86 numerically adjusts, in predetermined increments or decrements, the coefficients $\gamma_{1\text{-to-}y}$ of Equation (7) about their

$$\frac{\partial \xi_j}{\partial \gamma_k}$$

original values so that the derivatives:

are minimized for j = 2-to-4 and k = 1 to y (where y is the number of coefficients or weighing factors the function incorporates). For ξ_i to reach their minima, the derivatives (Equation (9)) should theoretically be or at least approach zero.

The predetermined increments and decrements define the resolution of the search for the optimal solution. If the increment and decrement values are small, the solution will be more precise, but will take longer to perform. The speed and processing capabilities of the host processor 30 and the desired degree of accuracy govern the selection of the increment and decrement values.

Once the coefficients $\gamma_{1\text{-tp-}y}$ are optimized, the calibration mode is complete. The optimized coefficients $\gamma_{1\text{-to-}y}$ are retained in Equation (6) for subsequent calculations of the navigation output 70 by the navigation algorithm 66.

When the electric field is to be sensed by one or more roving electrodes to generate the navigation output 70, as in the foregoing discussion, an alternative calibration mode can be employed, which commands the data acquisition module 38 to condition a navigation electrode, e.g., NE(i) (and not a roving electrode), to transmit electrical energy to the indifferent electrode 60, while also conditioning the same navigation electrode NE(i) to sense a local voltage amplitude $V_{NE(i)}$. In this alternative calibration mode, the data acquisition module 38 individually conditions the roving electrodes RE(1), RE(2), RE(3), and RE(4) to sense local voltage amplitudes, respectively $V_{RE(i)}$, where j=1-to-4, or $V_{RE(1)}$, $V_{RE(2)}$, $V_{RE(3)}$, and $V_{RE(4)}$. The data acquisition module 38 acquires the sensed local voltage amplitudes $V_{RE(1\text{-to-}4)}$. The calibration algorithm 86 derives the normalized detected voltage values $V_{N(1)}$ (or $V_{RE(1)}$ $/V_{NE(1)}$); $V_{N(2)}$ (or $V_{RE(2)}$ $/V_{NE(1)}$); $V_{N(3)}$ (or $V_{RE(3)}/V_{NE(1)}$); and $V_{N(4)}$ (or $V_{RE(4)}/V_{NE(1)}$). Since the spacing values for the roving electrodes RE(j) are known, the calibration algorithm 86 can optimize the coefficients $\gamma_{1\text{-to-}y}$ in the Equation (7) at each normalized voltage value $V_{N(1)}$; $V_{N(2)}$; $V_{N(3)}$;and $V_{N(3)}$ to yield a navigation output 70 which corresponds to the actual spacing values for the roving electrodes.

In an alternative navigation embodiment earlier discussed, the navigation output 70 is generated by sensing the electrical field by one or more navigation electrodes (instead of by one or more of the roving electrodes). With this alternative embodiment, the calibration mode commands the data acquisition module 38 to condition a navigation electrode, e.g., NE(1), to transmit electrical energy to the indifferent electrode 60, while also conditioning the same navigation electrode NE(1) to sense a local voltage amplitude $V_{NE(1)}$. In this alternative calibration mode, the data acquisition module 38 individually conditions the other navigation electrodes NE(2), NE(3), NE(4), and NE(5) to sense local voltage amplitudes, respectively $V_{NE(i)}$, where I=2-to-5, or $V_{NE(2)}$, $V_{NE(3)}$, $V_{NE(4)}$, and $V_{NE(5)}$. The data acquisition module 38 acquires the sensed local voltage amplitudes $V_{NE(2\text{-to-}5)}$. The calibration algorithm 86 derives the normalized detected voltage values $V_{N(2)}$ (or $V_{NE(2)}/V_{NE(1)}$); $V_{N(3)}$ (or $V_{NE(3)}/V_{NE(1)}$); $V_{N(4)}$ (or $V_{NE(4)}/V_{NE(1)}$), and $V_{N(5)}$ (or $V_{NE(5)}/V_{NE(1)}$). Since the spacing values for the navigation electrodes NE(i) are known, the calibration algorithm 86 can optimize the coefficients $\gamma_{1\text{-to-}y}$ in the Equation (7) at each normalized voltage value $V_{N(2)}$; $V_{N(3)}$;and $V_{N(3)}$ to yield a navigation output 70 which corresponds to the actual spacing values for the navigation electrodes.

When the navigation output 70 is generated by sensing the electric field using one or more navigation electrodes, an alternative calibration mode can be used, which commands the data acquisition module 38 to condition a roving electrode, e.g.,

RE(1) to transmit electrical energy to the indifferent electrode 60, while also conditioning the same roving electrode RE(1) to sense a local voltage amplitude $V_{RE(1)}$. At the same time, the data acquisition module 38 individually conditions the navigation electrodes NE(1), NE(2), NE(3), NE(4)and NE(5) to sense local voltage amplitudes, respectively $V_{NE(i)}$, where i=1-to-5, or $V_{NE(1)}$, $V_{NE(2)}$, $V_{NE(3)}$, $V_{NE(4)}$, and $V_{NE(5)}$. The data acquisition module 38 acquires the sensed local voltage amplitudes $V_{NE(1\text{-to-}5)}$. The calibration algorithm 86 derives the normalized detected voltage values $V_{N(1)}$ (or $V_{NE(1)}$ $/V_{RE(1)}$); $V_{N(2)}$ (or $V_{NE(2)}$ $/V_{RE(1)}$); $V_{N(3)}$ (or $V_{NE(3)}/V_{RE(1)}$); $V_{N(4)}$ (or $V_{NE(4)}/V_{RE(1)}$), and $V_{N(5)}$ (or $V_{NE(5)}/V_{NE(1)}$). Since the spacing values for the navigation electrodes NE(i) are known, the calibration algorithm 86 can optimize the coefficients $\gamma_{1\text{-to-}y}$ in the Equation (7) at each normalized voltage value $V_{N(2)}$; $V_{N(3)}$; $V_{N(4)}$; and $V_{N(5)}$ to yield a navigation output 70 which corresponds to the actual spacing values for the navigation electrodes.

As the foregoing discussion demonstrates, the navigation output 70 can be generated either by sensing using one or more of the roving electrodes or by sensing using one or more of the navigation electrodes. The calibration mode can be accomplished in four alternative ways, depending upon the methodology used for generating the navigation output. The four calibration modes are summarized in the following table:

Calibration Mode	Calibration: Transmitting Electrode	Calibration: Sense-Only Electrodes
1 (When the navigation output is to be generated by sensing the electric field using roving electrodes)	A Roving Electrode	Other Roving Electrodes
2 (When the navigation output is to be generated by sensing the electric field using roving electrodes)	A Navigation Electrode	The Roving Electrodes
3 (When the navigation output is to be generated by sensing the electric field using navigation electrodes)	A Navigation Electrode	Other Navigation Electrodes
4 (When the navigation	A Roving	The Navigation

Calibration Mode	**Calibration: Transmitting Electrode**	**Calibration: Sense-Only Electrodes**
output is to be generated by sensing the electric field using navigation electrodes)	Electrode	Electrodes

The coefficients can also be optimized based on other types of electric field information. For example, in an alternative embodiment, the calibration algorithm can optimize the coefficients by comparing voltages sensed at individual navigation or roving electrodes to the voltage V_N expected to be sensed, based upon the empiric voltage-to-distance function 72, i.e., Equation (5). This alternative calibration embodiment relies upon sensed individual voltages, and skips the derivational step of converting pairs of sensed voltages to spacing distances. In this embodiment, the calibration algorithm optimizes the coefficients by increments or decrements, using one of the already-described techniques, to bring the difference between sensed voltage and empiric expected voltage at individual electrodes to zero, or at least approaching zero. As in the first-described calibration mode, once the coefficients are optimized, they are retained by the

navigation algorithm 70 for subsequent calculations of the navigation output 70.

Furthermore, the calibration mode need not be accomplished by transmitting and sensing in a single energy field at the same point in time. A succession of energy fields, which are transmitted and sensed at different points in time, can be used for calibration purposes. A voltage difference between electrodes can be acquired, e.g., (i) by sensing, at a first point in time, a first voltage in an electrical field using a first navigation or roving electrode, (ii) by sensing at a second navigation or roving electrode, a second voltage in an electrical field generated at a later or earlier point in time, (iii) calculating an electrode spacing distance based upon the time-spaced voltage differentials, and (iv) comparing the calculated electrode spacing distance to the actual spacing distance, while optimizing the coefficients, in the manner already described.

C. Expressing the Navigation Output

The specific expression of the navigation output 70 can vary.

1. Proximity-Indicating Output

In one embodiment (see Fig. 3), the coefficients $\gamma_{1\text{-}tp\text{-}y}$ convert the normalized voltage amplitude to express the navigation output 70 as a voltage value ($V_{NAVIGATION\ OUTPUT}$). The navigation unit 20 includes a comparator 92, which receives as input the navigation voltage value. The comparator also receives as input a set line voltage 94, which constitutes a predetermined nominal voltage threshold value V_{THRESH}.

The comparator 92 compares the magnitude of voltage of the navigation output to the magnitude of V_{THRESH}.

The predetermined nominal voltage threshold value V_{THRESH} is selected according to an empirical voltage-to-distance function to establish a nominal separation distance between the marker electrode RE(1) and a given navigation electrode NE(i). The threshold voltage value V_{THRESH} serves to differentiate between a "close condition" between the marker electrode RE(1) and the given navigation electrode NE(i)(i.e., equal to or less than the nominal distance) and a "far condition" between the marker electrode RE(1) and a given navigation electrode NE(i)(i.e., greater than the nominal distance).

If the voltage of the navigation output $d(E_S-E_T)$ is greater than or equal to V_{THRESH}, the comparator generates a proximity-indicating output, also designed $P_{(i)}$, for the navigation electrode NE(i). The proximity-indicated output $P_{(i)}$ for a given navigation electrode NE(i) notifies the physician that the requisite "close condition" exists between the marker electrode RE(1) and the particular navigation electrode NE(i).

When the voltage of navigation output $d(E_S-E_T)$ is less than V_{THRESH}, the comparator generates no output for the navigation electrode NE(i). The absence of a proximity-indicating output $P_{(i)}$ for a particular navigation electrode P(i) notifies the physician that the requisite default "far condition" exists between the marker electrode RE(1) and the particular navigation electrode NE(i).

The magnitude selected for the threshold value V_{THRESH} sets the spacial criteria for "close condition" and "far condition," given the physical characteristics of the marker electrode RE(1) and the physical characteristics of the navigation electrodes NE(i). The physical characteristics include the diameter and shape of the electrodes, as well as the electrical conductivity of the material or materials from which the electrodes are made and the electrical properties of the conductive medium existing between the marker electrode RE(1) and the navigation electrode NE(i) (for example, a blood pool or tissue mass).

The value of V_{THRESH} can be set at a desired fixed voltage value representing a nominal threshold distance. In the illustrated and preferred embodiment (see Fig. 3), the navigation unit 20 includes an input 96 by which the physician can designate a value for the nominal distance. For example, the physician can designate the nominal distance within a range of distances of, e.g., 1 mm to 5 mm. The navigation unit 20 can include a look-up table or its equivalent, which expresses the empirically determined relationship between voltage and distance. Using the table, the navigation unit 20 converts the distance value entered by input to a corresponding normalized voltage value, which constitutes V_{THRESH}. The navigation unit 20 also includes a voltage regulator 98, which sets the voltage line input 94 to the normalized voltage value (V_{THRESH}), to thereby achieve the spacial sensitivity established by the physician for the proximity-indicating output $P_{(i)}$.

Further details of this manner of proximity sensing can be found in copending Patent Application Serial No. 08/938,296, filed September 26,1997, and entitled "Systems and Methods for Generating Proximity-Indicating Output for Locating and Guiding Operative Elements within Interior Body Regions."

2. Three-Dimensional Navigation Output (Differential Phase Analyses)

The navigation unit 20 can also sense other electrical characteristics of the field 64 to assess three-dimensional directional information regarding the orientation of the marker electrode RE(1) relative to one or more navigation reference probes 22.

For example, the phase and peak amplitude input signal 88 (see Fig. 1) generated by the data acquisition unit 38 can also be processed by the navigation algorithm 66 to indicate the location of the marker electrode RE(1) horizontally above or below the navigation reference probe 22, or horizontally to the left or to the right of a given navigation electrode NE(i).

If the switched-on navigation electrodes NE(i) are located above the position of the marker electrode RE(1), the output voltage signal of the amplifier 40 will be out of phase with respect to the phase of the oscillator 58 (which is sensed at the switched-on navigation electrode NE(i)); that is, analog signal received by the sample and hold element 54 will have a (-) sign. Conversely, if the switched-on navigation electrodes NE(i) are located below the

position of the marker electrode RE(1), the output voltage signal of the amplifier 40 will be in phase with respect to the phase of the oscillator 58.

Using empiric coefficients and weighing factors, the navigation algorithm 66 determines where the output of the peak detector 50 changes sign, by turning from (-) to (+) or vice versa. This transition point fixes the horizontal up or down orientation of the marker electrode RE(1) relative to the navigation reference probe 22.

Similarly, the synchronization of the phase of the output voltage signal of the amplifier 40 with the phase of the oscillator 28 along the axis of the navigation reference probe 22 indicates whether the marker electrode RE(1) is horizontally to the left or right of a given navigation electrode NE(i). A differential phase comparison will yield an out-of-phase condition when the marker electrode RE(1) is not longitudinally oriented with respect to a given navigation electrode NE(i). Conversely, the differential phase analysis will yield an in-phase condition when the marker electrode RE(1) is oriented within an iso-potential surface that the switched-on navigation electrode NE(i) transmits. The synchronization of the phase thus indicates whether the marker electrode RE(1) is horizontally to the left or right of the iso-potential surface associated with a given navigation electrode NE(i).

Like the AC voltage signal 46, the peak amplitude detected by the detector 50 will also vary according to the proximity of the selected navigation electrode NE(i) to the marker electrode RE(1).

Sensing multiple electrical field parameters provides three-dimensional navigational output, with coordinate factors expressing horizontally above or below orientation, left or right orientation, and radial close or far orientation. Further details can be found in copending Patent Application Serial No. 08/320,301, filed October 11, 1994, and entitled "Systems and Methods for Guiding Movable Electrode Elements Within Multiple Electrode Structures."

3. Three-Dimensional Navigation Output (Differential Waveform Analyses)

As another example, the data acquisition module 38 can be commanded by the host processor 30 to provide waveform data sensed by the marker electrode RE(1), as well as waveform data sensed by each switch-on navigation electrode NE(i). Applying empiric coefficients and weighing factors, the navigation algorithm 66 processes waveform data to differentially assess the phase of the waveforms.

The differential waveform comparison will yield an out-of-phase condition when the marker electrode RE(1) is not longitudinally oriented with respect to a given navigation electrode NE(i). Conversely, the differential waveform analysis will yield an in-phase condition when the marker electrode RE(1) is oriented within an iso-potential surface that the switched-on navigation electrode NE(i) transmits. The synchronization of the waveform this indicates whether the marker electrode RE(1) is horizontally to the left or right of a given navigation electrode NE(i).

Further details of this analysis can be found disclosed in copending Patent Application Serial No. 08/745,795, filed November 8, 1996, and entitled "Systems and Methods for Locating and Guiding Operating Elements Within Interior Body Regions."

4. Multiple Navigation Marker Probes

Fig. 4 shows a representative implementation of a three-dimensional navigation system 200, which includes three navigation reference probes 204, 206, and 208 positioned within an interior body region R. Each probe 204, 206, and 208 carries an array of navigation electrodes NE(i), as already described.

An operative element 202 is deployed for movement within the region R. The operative element 202 carries a marker electrode RE(1), as well as two calibration electrodes RE(2) and RE(3), as already described.

The navigation electrodes NE(i) and roving electrodes RE(j) are coupled to the navigation unit 20, in the same fashion shown in Fig. 1. In the manner previously described, controlled by the navigation unit 20, the navigation electrodes NE(i) transmit an electrical field F. Also under the control of the navigation unit 20, the navigation electrodes NE(i) and the marker electrode RE(1) sense differential electrical conditions in the field. After sensed electrical field conditions are processes, the navigation unit 20 provide a navigation output 70 for locating the operative element 202.

As shown in Fig. 4, the three reference probes 204, 206, and 208 are purposely situated within the region R to provide spaced-apart navigational points for locating the operative element 202. Furthermore, the probes 204, 206, and 208 are preferably located at different coordinate planes, so that the probe axes extend in mutually nonparallel relationships, to create a three-dimensional navigational grid and make triangulation possible.

The probes 204, 206, and 208 can be individually placed at or near known anatomic regions within the region R, using, for example, fluoroscopy or another imaging technology, such as ultrasound. It should be appreciated that a single locating probe or multiple locating probes may be positioned essentially in any region within the region R or in contact with tissue or a vascular region surrounding the region R for purposes of establishing navigational points of reference to locate the operative element 202. Any region of placement with the body that can be imaged by fluoroscopic or other imaging technology can be selected as a potential navigational site. The region of placement therefore does not have to represent a particular fixed anatomic site. A navigation probe may even be placed outside the patient's body.

The acquisition and processing of sensed electrical signal data within the field F using the system 200 of multiple navigation electrodes NE(i) located within the space S provide a robust, three-dimensional navigation output 70.

D. Displaying the Navigation Output

In the illustrated embodiment (see Figs. 1 and 5), the system 10 includes an output display device 90 coupled to host processor 30 to present the navigation output 70. The display device 90 may present the navigation output 70 in various ways.

For example, in the illustrated embodiment (see Fig. 5), the device 90 presents the presence or absence of proximity-indicating outputs $P_{(i)}$ (previously described) in a visual or graphic format useful to the physician for remotely locating and guiding the operative instrument 14 relative to the navigation reference probe 22 or probes.

As Fig. 5 shows, the output display device 90 can comprise a Graphical User Interface (GUI) 98. In the illustrated embodiment, the GUI 98 is implemented by a graphical control program 100 resident in an external microprocessor based computer control, such as a laptop computer 164 having a keyboard 166, a display screen 168, and mouse 170. The laptop computer 164 is coupled to the host processor 30 via a communication port 172, such as RS 232 or an Ethernet™ connection.

The host processor 30 conditions the GUI graphical control program 100 to generate on the display screen 168 an idealized graphical image 174, which models the geometry of the particular navigational probe 22 or probes deployed in the body region 12. The image 174 of the navigation probe can appear, e.g., as a modeled wire-frame image, with the navigation electrodes NE(i) spatially arranged and appearing as nodes 180.

The GUI control program 100 initializes the nodes 180 on the model image 174 at a designated color or shade. The initialized color or shade for a given node 180 constitutes a visual signal to the physician, that the operative instrument 14 (and, in particular, the marker electrode RE(1)) is at a "far condition" relative to the associated navigation electrode.

The proximity-indicating output $P_{(i)}$ generated by the navigation algorithm 66 for a given navigation electrode NE(i) is transmitted to the control program 100. The control program 100 switches "ON" the node 180 marking the location of the given navigation electrode NE(i) in the image 174, by changing the designated color or shade (as Fig. 5 shows). The node 180, when switched "ON," displays a different color or shade, e.g., green, to visually signal the physician that the operative instrument 14 is in a "Close Condition" relative to the corresponding navigation electrode NE.

The foregoing GUI 98 and implementing control programs can be implemented using the MS WINDOWS™ application and the standard controls provided by the WINDOWS™ Development Kit, along with conventional graphics software disclosed in public literature. Other details of the GUI 98 can be found in copending patent application Serial No.08/938,721, filed September 26, 1997, and entitled "Systems and Methods for Generating Images of Structures Deployed Within Interior Body Regions.".

Various features of the invention are set forth in the following claims.

What is Claimed:

1. A calibrated system for locating a roving structure inside a body region by use of an electric field established inside the body region between an electrical energy transmitting electrode and an electrical reference, comprising:

first and second electrodes spaced apart in the electric field by a known distance,

a processing element which derives a navigational output for the roving structure based upon a function, wherein the function expresses a relationship between an electrical characteristic sensed at the roving structure and distance between the roving structure and the electrical energy transmitting electrode, and

a calibration element which adjusts the function by comparing the known distance to at least one derived navigation output derived by the processing element based upon the function by sensing an electrical characteristic at the first and second electrodes.

2. A calibrated system according to claim 1,

wherein the roving structure carries the first and second electrodes.

3. A calibrated system according to claim 2,

wherein one of the first and second electrodes comprises the electrical energy transmitting electrode.

4. A calibrated system according to claim 2,

wherein the roving structure includes a code identifying the known distance, and

wherein the calibration element includes an input to upload the code.

5. A calibrated system according to claim 1, further comprising a navigation structure, separate from the roving structure, wherein the navigation structure carries the first and second electrodes.

6. A calibrated system according to claim 5,

wherein one of the first and second electrodes comprises the electrical energy transmitting electrode.

7. A calibrated system according to claim 5,

wherein the navigation structure includes a code identifying the known distance, and

wherein the calibration element includes an input to upload the code.

8. A calibrated system according to claim 1,

wherein the function comprises a voltage-to-distance function.

9. A calibrated system according to claim 1,

wherein the function comprises a voltage gradient-to-distance function.

10. A calibrated system according to claim 1,

wherein the function comprises an impedance-to-distance function.

11. A calibrated system according to claim 1,

wherein the function comprises a coefficient that is adjusted based upon a comparison of the derived navigation output and the known distance.

12. A calibrated system according to claim 1,

wherein the function includes a coefficient that is optimized based upon a comparison of the derived navigation output and the known distance.

13. A calibrated system according to claim 1,

wherein the function includes a coefficient, and wherein the calibration element iteratively adjusts the coefficient in predetermined increments or decrements to minimize deviation between the derived navigation output and the known distance.

14. A calibrated system according to claim 1,

wherein the processing element drives a normalized electrical characteristic by dividing the electrical characteristic sensed by either one of the first and second electrodes by a corresponding electrical characteristic sensed by the electrical energy transmitting electrode, and

wherein the function expresses a relationship between the normalized electrical characteristic and distance between the one electrode and the electrical energy transmitting electrode.

15. A calibrated system according to claim 1,

wherein the processing element drives a normalized electrical characteristic by dividing the electrical characteristic sensed by either one of the first and second electrodes by a corresponding electrical characteristic sensed by the electrical energy transmitting electrode, and

wherein the function expresses a relationship between the normalized electrical characteristic and distance between the one electrode and the electrical energy transmitting electrode.

16. A calibrated system according to claim 1,

wherein the processing element generates a proximity-indicating output based upon variance between the navigation output and a threshold value.

17. A calibrated system according to claim 1, further comprising a device for displaying the navigation output.

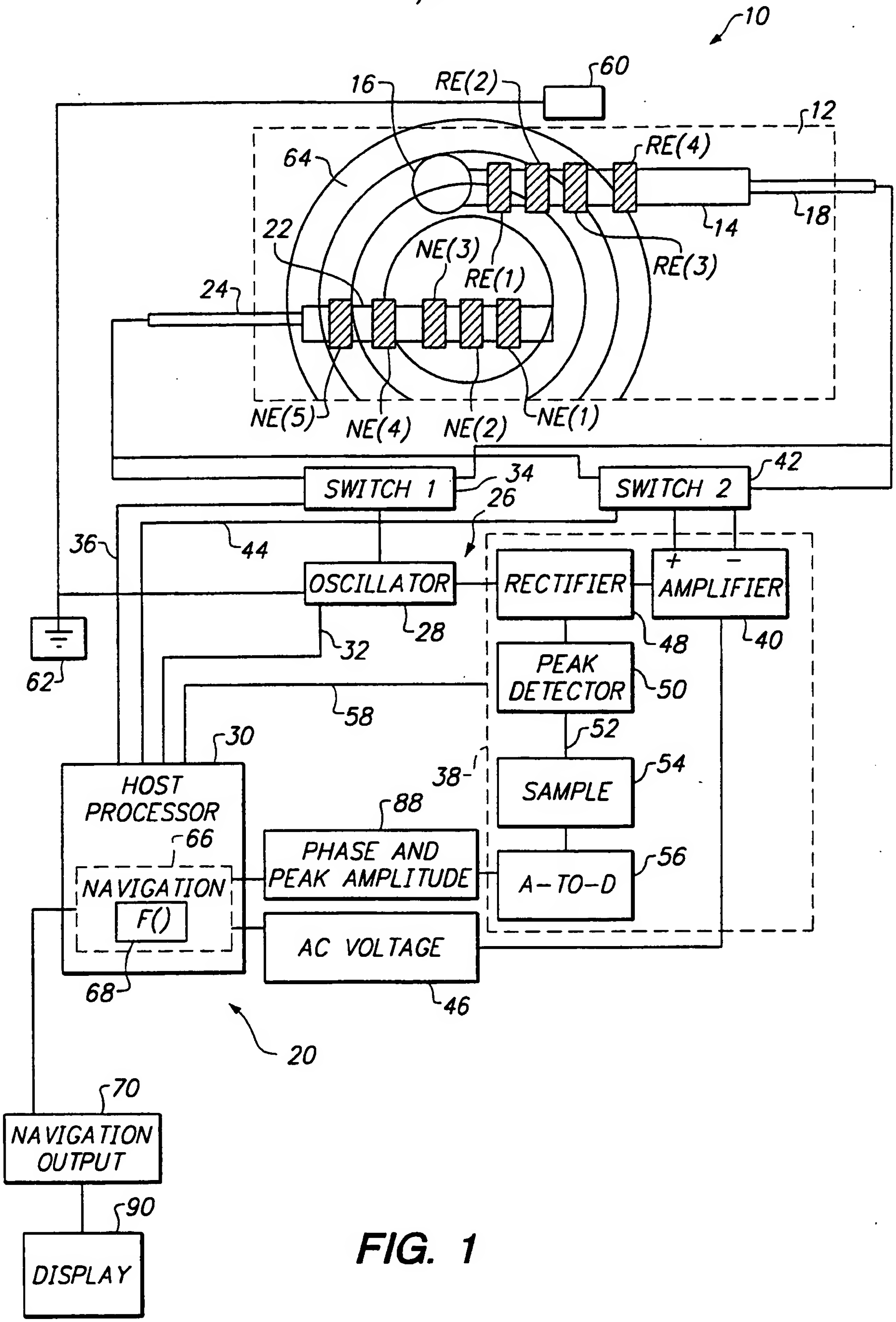
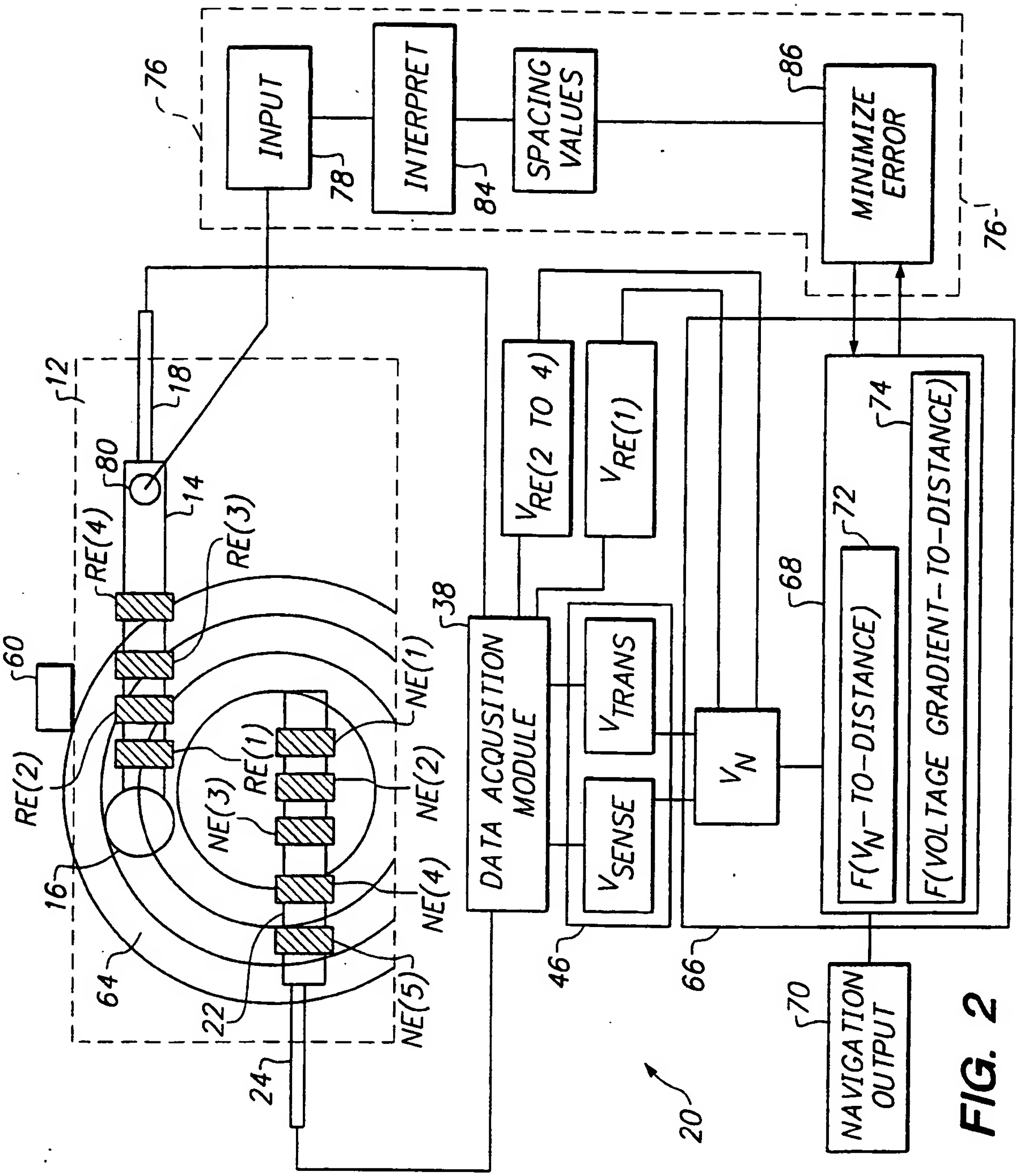

10
16
RE(2)
60
12
64
RE(4)
14
18
22
NE(3)
RE(3)
RE(1)
24
NE(5)
NE(4)
NE(2)
NE(1)
SWITCH 1
34
SWITCH 2
42
26
36
44
OSCILLATOR
RECTIFIER
+ −
AMPLIFIER
62
32
28
48
40
PEAK DETECTOR
50
58
52
30
HOST PROCESSOR
38
SAMPLE
54
66
88
NAVIGATION
PHASE AND PEAK AMPLITUDE
A−TO−D
56
F()
AC VOLTAGE
68
46
20
70
NAVIGATION OUTPUT
90
DISPLAY

FIG. 1


INPUT
INTERPRET
SPACING VALUES
MINIMIZE ERROR
76
78
84
86
76
12
18
80
14
RE(4)
RE(3)
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RE(1)
NE(1)
NE(2)
NE(3)
NE(4)
NE(5)
16
64
22
24
38
DATA ACQUSITION MODULE
$V_{RE}(2\ TO\ 4)$
$V_{RE}(1)$
V_{TRANS}
V_{SENSE}
V_N
46
66
68
72
74
$F(V_N$-TO-DISTANCE)
F(VOLTAGE GRADIENT-TO-DISTANCE)
70
NAVIGATION OUTPUT
20

FIG. 2

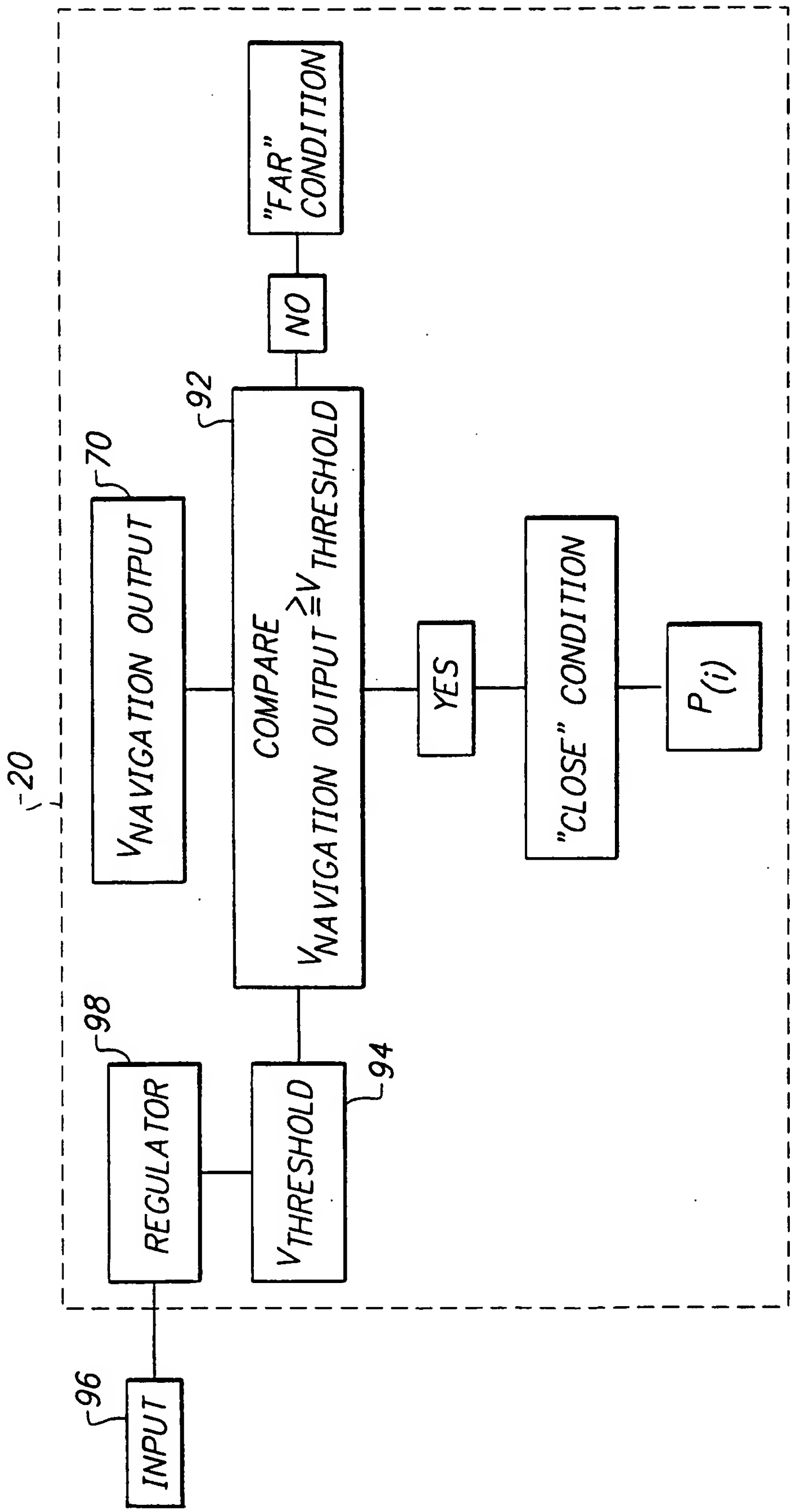
"FAR" CONDITION
NO
92
70
$V_{NAVIGATION}$ OUTPUT
COMPARE
$V_{NAVIGATION}$ OUTPUT $\geq V_{THRESHOLD}$
YES
"CLOSE" CONDITION
$P_{(i)}$
20
98
REGULATOR
$V_{THRESHOLD}$
94
96
INPUT

FIG. 3

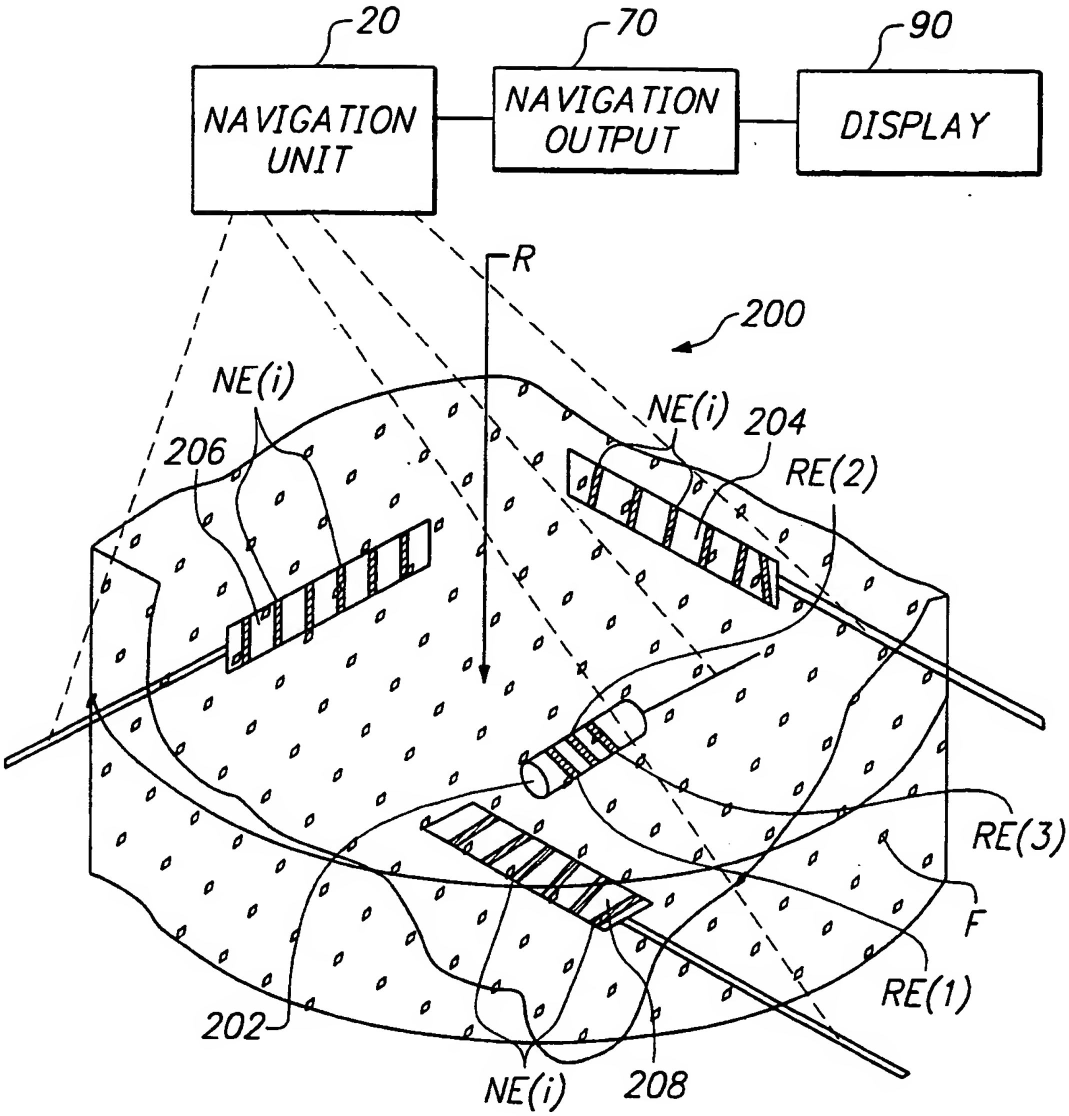
20
NAVIGATION UNIT
70
NAVIGATION OUTPUT
90
DISPLAY
R
200
NE(i)
206
NE(i)
204
RE(2)
RE(3)
F
RE(1)
202
NE(i)
208

FIG. 4

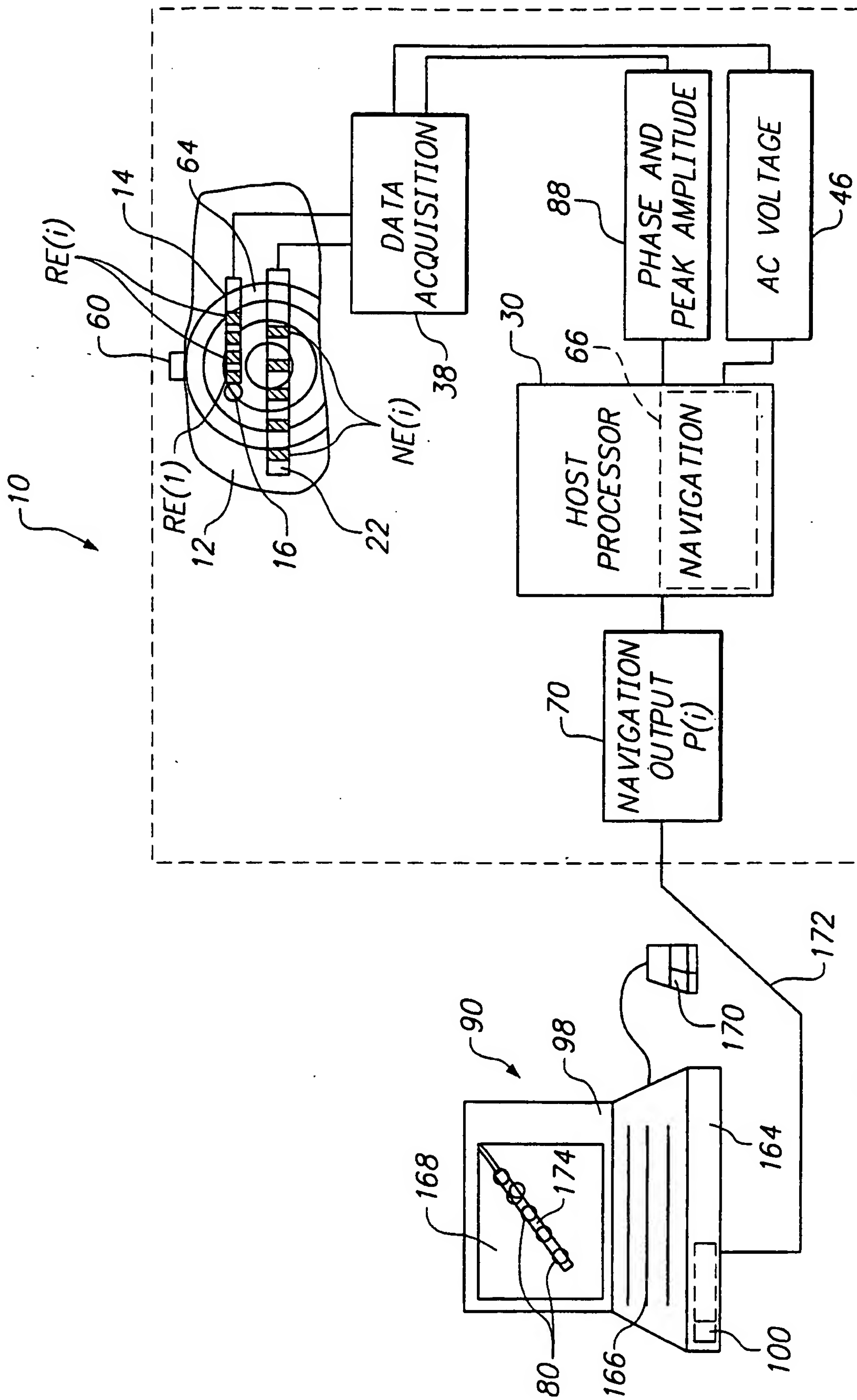
10
RE(i)
14
64
60
RE(1)
12
16
22
NE(i)
38
DATA ACQUISITION
88
PHASE AND PEAK AMPLITUDE
AC VOLTAGE
46
30
66
HOST PROCESSOR
NAVIGATION
70
NAVIGATION OUTPUT P(i)
172
170
90
98
168
174
164
80
166
100

FIG. 5

INTERNATIONAL SEARCH REPORT

Inte. .onal Application No
PCT/US 99/07679

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 553 611 A (BUDD ET AL.) 10 September 1996 (1996-09-10) abstract; figures 1,2 ---	1-17
A	WO 96 05768 A (BEN HAIM ET AL.) 29 February 1996 (1996-02-29) abstract; figures 1,4,10A-D,14 ---	1-17
A	EP 0 829 229 A (SIEMENS ELEMA AB) 18 March 1998 (1998-03-18) abstract; figures 1-3 ---	1-17
A	WO 97 29710 A (BEJERANO ET AL.) 21 August 1997 (1997-08-21) abstract; figures 1-4 -----	1-17

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 July 1999	29/07/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Michels, N

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/07679

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
US 5553611	A	10-09-1996	NONE			
WO 9605768	A	29-02-1996	AU	1693095	A	14-03-1996
			CA	2197986	A	29-02-1996
			CN	1168625	A	24-12-1997
			EP	0776176	A	04-06-1997
			EP	0894473	A	03-02-1999
			JP	10507104	T	14-07-1998
			US	5738096	A	14-04-1998
EP 0829229	A	18-03-1998	JP	10094609	A	14-04-1998
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WO 9729710	A	21-08-1997	AU	1616897	A	02-09-1997
			AU	1731597	A	02-09-1997
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